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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/307,633	05/07/1999	KENNETH J. NIEHOFF	L-F/104H	5115

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EXAMINER	
AHMED, AAMER S	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/307,633	NIEHOFF, KENNETH J.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,24,26,28 and 30* is/are rejected.

7)☒ Claim(s) *23,25,27,29 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 August 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amended specification and drawings have been accepted and objections withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22, 24, 26, 28 and 30 are rejected under 35 U.S.C. 1O3(a) as being unpatentable over Reilly et al. (US 5,383,858 A), in view of Applicant's disclosure on Page 3, lines 7-33, or alternatively in view of Stade (US 4,636, 198 A). Reilly et al. discloses a front-loading medical injector, which may be used with a standard empty syringe (to be filled at the time of use) or a pre-filled syringe (22), comprising a body (32) having a closed forward end (34/36) with a nozzle (86), an open rearward end, and including structure mountable in an injector (27), a plunger (38) located within the body, the empty syringe and the pre-filled syringe both having a capacity, and physical indicia (70/70b/70s) interacting with the injector on one of the syringes indicating information related to the capacity of the syringe, i.e. the dimensions of the syringe, the content (defined as the amount of specified material contained, see Merriam Webster's Collegiate Dictionary (tenth edition) © 1997, content on page 250) of the syringe in the case of a

pre-filled syringe, manufacturing information, recommended contrast media flow rates/pressures, and loading/injection sequences, see Column 6, lines 45-51.

Reilly et al. fails to disclose the pre-filled syringe being pre-filled to a capacity with an amount of fluid different than a first capacity of an empty syringe. Applicant's admission of prior art on Page 3, lines 21-25 of Applicant's originally filed specification, discloses pre-filled syringes are sold in a number of capacities, e.g. ranging from 50 to 125 milliliters, allowing the operator preparing for an injection to select a syringe containing only as much media as is needed for the injection', and on Page 4, lines 2-8, discloses in Figure IB a prior art pre-filled syringe having an extender (16). It would have been obvious to one having ordinary skill in the art to have modified Reilly et al.'s front-loading medical injector with a pre-filled, disposable syringe including an extender, so as to allow the syringe to be filled with only as much media as will be needed, thereby preventing infection due to contamination and allowing for cost-effective dosing to minimize waste and in order to accurately measure and record the amount of reagent delivered.

Alternatively, Stade discloses a power syringe with volume reducing adapters comprising a power injector (45), a syringe body (30) having a closed forward end (A, see labeled figure on next page) having a nozzle (48), an open rearward end (46), a plunger (32) located within the body. The power injector may be used with pre-filled syringes having standard dimensions, standard pistons, and different content volumes by way of volume reducing adapters having various fluid displacing lengths.

It would have been obvious to one having ordinary skill in the art to have utilized Reilly et al.'s front-loading medical injector with pre-filled syringes having volume reducing adapters

therein as taught by Stade, so as to provide a syringe for containing a reduced volume of contrast media which is suitable for being utilized in existing power injectors, and to avoid costs associated with the manufacture, inventory and supply of different syringe sizes. Furthermore, Hyde U.S. Patent 2,966,175 provides support for providing volume and capacity indicia on syringes as described by Reilly et al (Hyde col. 4 line 31 and col. 5 line 36).

Claims 22, 24, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stade (US 4,636, 198 A) in view of Reilly et al. (US 5,383,858 A). Stade discloses a power syringe with volume reducing adapter comprising a power injector (45), a syringe body (30) having a closed forward end (A, see labeled figure above) with a nozzle (48), an open rearward end (46), a plunger (32) located within the body. The power injector may be used with pre-filled syringes having standard dimensions, standard pistons, and different content volumes by way of volume reducing adapters having various fluid displacing lengths. Stade fails to disclose a physical indicia interacting with the injector on the syringe indicating information related to the capacity of the syringe. Reilly et al. discloses a front-loading medical injector, which may be used with a standard syringe to be filled at the time of use or a pre-filled syringe (22), comprising a body (32) having a closed forward end (34/36) with a nozzle (86), an open rearward end, and including structure mountable in a common injector (27), a plunger (38) located within the body, the empty syringe and the pre-filled syringe both having a capacity, and physical indicia (70/7Ob/70s) interacting with said common injector on one of the syringes indicating information related to the capacity of the syringe, i.e. the dimensions of the syringe, the content (defined as the amount of specified material contained, see Merriam Webster's Collegiate Dictionary (tenth edition) © 1997, 4 250) of the syringe in the case of a pre-filled syringe,

manufacturing content on page information, recommended contrast media flow rates/pressures, and loading/injection sequences see Column 6, lines 45-51. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified Stade's syringe with a physical indicia capable of interacting with the injector to indicate information related to the capacity of the syringe, so as to enable the injector to read the physical indicia on the syringe and to cause the generation of signals therefrom to regulate the injector controller in order to adjust the function (i.e. flow rates and pressures) of the injector accordingly. Furthermore, Hyde U.S. Patent 2,966,175 provides support for providing volume and capacity indicia on syringes as described by Reilly et al (Hyde col. 4 line 31 and col. 5 line 36).

Claims 22, 24, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fenton, Jr. et al. (US 4,652,260 A) in view of Stade (US 4,636, 198 A). Fenton, Jr. et al. discloses an infusion device/powered syringe, for use with different size syringes, the syringes respectively comprising a body (20) having a closed forward end (138) with a nozzle (14û) and an open rearward end (no reference numeral, interpreted as the end adjacent flange (158) which slidably receives plunger rod (34, the body of each syringe having a diameter and including structure mountable in a common injector (1%, a plunger (no reference numeral, interpreted as the piston (not shown) at the distal end of plunger rod (34)) located within the body, the syringes having different capacities, and physical indicia (126) interacting with the common injector on one syringe indicating information related to the capacity of said syringe.

Fenton, Jr. et al. fails to disclose the different sized/capacity syringes having a common diameter. Stade discloses a power syringe with volume reducing adapters comprising a power injector (45), a syringe body (30) having a closed forward end (A, see labeled figure on next

page) having a nozzle (48), an open rearward end (46), a plunger (32) located within the body. The power injector may be used with pre-filled syringes having standard dimensions, standard pistons, and different content volumes by way of volume reducing adapters having various fluid displacing lengths. It would have been obvious to one having ordinary skill in the art to have modified Fenton, Jr. et al. with syringes having different capacities via volume reducing adapters, while maintaining the same diameter so as to avoid costs associated with the manufacture, inventory and supply of different syringe sizes.

Allowable Subject Matter

Claims 23, 25, 27, 29 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed August 9, 2005 have been fully considered but they are not persuasive. Applicant argues that Reilly does not suggest encoding information relating to the capacity of the syringe onto indicia. However, Reilly does disclose that information can be encoded on the encoding device and it would have been obvious to one having ordinary skill in the art at the time of invention by applicant to include information pertaining to the capacity of the syringe. Hyde discloses a similar device and provides support for this obvious inclusion of volume and capacity information (col. 4 line 31).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700